



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g1905d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 29, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 13

Ethel V. Slack
President
Slacks, Incorporated
W12153 Slack Rd.
Lodi, Wisconsin 53555

Dear Ms. Slack:

The Food and Drug Administration (FDA) conducted an inspection of your Slacks, Inc. facility located at W12153 Slack Road, Lodi, WI, on July 12 and 16, 2001. During the inspection, the FDA investigator documented violations of Section 403(q)(1) of the Federal Food, Drug and Cosmetic Act (the Act) and deviations from its implementing regulations contained in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). These deviations cause your products, Ol' Snort brand regular "Salsa" and "Rip-Snortin' Super Hot Formula," to be misbranded within the meaning of the Act, in that:

1. The Ol' Snort brand regular Salsa and Rip-Snortin' Super Hot Formula Salsa are misbranded under 403(q)(1) of the Act because the nutrition information is not in one of the formats defined in 21 CFR 101.9(d). [See 21 CFR 101.9(j)(1)(I).] In addition, the labels bear a nutrient content claim, which also subjects the food to the nutrition labeling requirements. (See item #2 regarding the nutrient content claim.)
2. The products are misbranded under Section 403(r)(1)(A) of the Act because the labels bear the claim "QUALIFIES AS LOW SODIUM" but the products do not meet the requirements for "low sodium" as described in 21 CFR 101.61(b)(4)(i)(B). A food may bear a "low sodium" claim if the food has a reference amount of 30 grams or less or 2 tablespoons or less and contains 140mg or less sodium per reference amount and per 50 g. These products do not contain 140 mg of sodium or less per 50 g.

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Ethel V. Slack
October 29, 2001

Neither this letter nor the form FDA-483, Inspectional Observations, issued at the conclusion of the inspection are meant to be an all-inclusive list of deficiencies that may exist at your facility. It is your responsibility as top management to ensure that your establishment is in compliance with all requirements of Federal regulations.

You should notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include seizure, injunction and/or the issuance of an order requiring a permit before delivery for introduction or introducing your acidified products into interstate commerce. Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated on the letterhead.

Additionally, the sodium content for both products is identified as "106 mg." This is not in the format required by 21 CFR 101.9(c)(4) which states that sodium in amounts of 5 to 140 milligram are to be listed in 5 milligram increments. This deviation should be corrected when new labels are printed. When approved labels are available, forward a copy of the revised label to Compliance Officer Wisecup at the address indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

TSW/ccl
